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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,740

10/20/2006

Jose Hermida Santos

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

09/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,740	<b>Applicant(s)</b> SANTOS ET AL.	
	<b>Examiner</b> Bao-Thuy L. Nguyen	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 12-19 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6-11, 20-25, 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species I-3 (obstetric complications) and Species II-2 (polypeptide) in the reply filed on 18 May 2009 is acknowledged. The traversal is on the ground(s) that the EPO has already reviewed the unity of the invention and determined that all claims met the requirement of unity of invention. This is not found persuasive because in a national stage application all questions of substance and within the scope of the requirements of the treaty and regulations, procedure in an international application designated the United States shall be determined as in the case of national applications regularly filed in the Office, including (1) questions relating to form and contents of the application in accordance with the requirements of the treaty and the Regulations; (2) the question of unity of invention to be reexamined under section 121 of this title, within the scope of the requirements of the treaty and the Regulations; and (3) a verification of the translation of the international application or any other document pertaining to the application if the application or other document was filed in a language other than English. See 35 USC 372. Since the instant claims lack a common technical feature as stated in the requirement dated 20 March 2009, a restriction requirement is still deemed proper and is therefore made FINAL.

2. Claims 2-5, 12,-19 and 35-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 18 May 2009.

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3. This application contains claims drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Claims 1, 6-11, 20-25 and 34 are under consideration.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is vague because it depends on non-elected claim 1.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 6-11 and 20-25 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Hurtado et al (*Blood*. September 1, 2004. Vol. 104, No. 5, PP. 1369-1374. Prepublished online May 18, 2004).

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Hurtado et al discloses endothelial protein C receptor (EPCR) and its role in the anticoagulant system and in placental development. Hurtado discloses that anti-EPCR autoantibodies may be involved in clinical manifestations of APS and in fetal loss and set out to prove this hypothesis with an ELIZA. See abstract. Hurtado teaches anchoring EPCR preserving its extracellular epitopes to microplates, adding samples from patients, Bound IgM and IgG anti-EPCR autoantibodies were detected with either a peroxidase-conjugated murine polyclonal antihuman IgM or an alkaline phosphatase-conjugated murine polyclonal antihuman IgG. See page 1370, second column, *Enzyme-linked immunosorbent assay for the determination of anti-EPCR autoantibodies*. Hurtado discloses that high levels of autoantibodies to EPCR were detected in woman with previous history of multiple episodes of fetal death. See page 1373.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado in view of Kurosawa et al (US 2005/0032140).

Hurtado differs from the instant claim in failing to teach a kit comprising all of the reagents of an ELiZA for detecting autoantibodies to EPCR.

However, commercial ELiZA kits are well known in the art as demonstrate by Kurosawa. See paragraph [0012] and [0133].

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the reagents necessary for an ELISA taught by Hurtado into kits taught by Kurosawa because kits are well known in the art for providing the advantage of convenience and economy. A skilled artisan would have had a reasonable expectation of success in assembling the reagents of Hurtado into kits because doing so would lead to a predictable solution.

### *Conclusion*

**10.** No claim is allowed.

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
04 September 2009